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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,731	06/23/2003	Joseph Raymond Faryniarz	J6829(C)	7564

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UNILEVER INTELLECTUAL PROPERTY GROUP
700 SYLVAN AVENUE,
BLDG C2 SOUTH
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,731	FARYNIARZ ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/03; 1/23/04</u> | 6) <input type="checkbox"/> Other: _____ |

PD

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DETAILED ACTION

Receipt of the Information Disclosure Statements filed 6/23/03 and 1/23/04 is acknowledged.

Claims 1-7 are pending in this application.

Priority

Priority to US provisional 60/455330 filed 3/17/03 is acknowledged.

Information Disclosure Statement

The information disclosure statements of 6/23/03 and 1/23/04 have been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/61107 to Beerse et al.

Beerse discloses an antimicrobial wipe that is impregnated with an antimicrobial cleansing composition. See abstract. Specifically example 14 discloses a composition comprising 3.20% sodium malonate, additional components, and the balance water (84.03% of the carrier). The wipe is suitable for application to the human skin to remove oil and dirt. Further, the composition is useful for treatment of acne and improvement of skin appearance. The improvement includes providing a smoother and more even appearance of the skin and regulating the signs of aging (wrinkles, fine lines, sagging, loss of skin's firmness, etc). See page 4, lines 25-36 and in particular page 5, lines 1-30.

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With regard to the recitation of “wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test”, it is the examiner’s position that Beerse’s composition will inherently have a Flexibility value of greater than 1 and the rationale is as follows: Firstly, the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Secondly, the prior art teaches the same malonic acid salt and in the same weight percent. Therefore, since the prior art’s composition and the instant composition, which recites open-claim language, are to be identical, it is the examiner’s position that they will exhibit the same property, i.e. the instant flexibility value. It should be noted that once an examiner has presented evidence or reasoning tending to show inherency, the burden shifts to the applicant to show it is not inherent. See MPEP 2112.01.

Claims 1, 4, and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Apperson et al (2,586,288).

Apperson et al disclose an aluminum sulfamate antiperspirant. Specifically example 6 disclose a composition comprising 11.9% diammonium malonate and 44.1% water (carrier), among other components. Apperson discloses the application of the composition to the skin. See column 3, lines 47-61.

With regard to the recitation of “wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test”, it is the examiner’s position that Apperson’s composition will inherently have a Flexibility value of greater than 1 and the rationale is as follows: Firstly, the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Further, Table VIII of the instant specification discloses ammonium malonate exhibits a value of 1.36. Secondly, the prior art

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teaches the same malonic acid salt and in the same weight percent. Therefore, since the prior art's composition and the instant composition, which recites open-claim language, are identical, it is the examiner's position that they will exhibit the same property, i.e. the instant flexibility value. It should be noted that once an examiner has presented evidence or reasoning tending to show inherency, the burden shifts to the applicant to show it is not inherent. See MPEP 2112.01.

With regard to claim 6, it is the examiner's position that although the prior art does expressly teach the instant preamble of "A method of controlling signs of aging...", this preamble will inherently be met by the prior art for the following reasons: Apperson teaches the same method steps, i.e. the body of the claim, wherein Apperson teaches applying the same composition (a cosmetic composition comprising a malonate salt in the same weight percent and a carrier in the same weight percent) to the skin. Therefore, since the method steps are the same and the composition is applied to the same population, the preamble will inherently be met.

Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jokura et al (5,641,495).

Jokura discloses a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) **a salt of a dicarboxylic acid**. See abstract. Jokura discloses that examples of the dicarboxylic acid utilized **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid. The dicarboxylic acid salt (C) include alkali metal (for example, sodium, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; **alkanolamine** (for example, triethanolamine) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. Note that the term amine encompasses Jokura's alkanolamines, arginine,

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lysine, and ammonium. To achieve a sufficient moisturizing effect while avoiding excessive irritation, the content of these components (B) and (C) in the skin cosmetic of the present invention falls within a range of from 0.01 to 20% by weight, still preferably from 0.05 to 15% by weight and still preferably 0.01 to 10% by weight. See column 3, lines 50-60. When oily substances are used as the carrier, the content of the oily substance in is a range from 0.01 to 50% by weight. See column 4, lines 14-16. When water, ethanol and/or water-soluble polyhydric alcohols are employed as the carrier, the content is preferably from 0.01 to 95% by weight. See column 4, lines 30-35.

The composition is used for treating dry skin in the winter and applicable to the skin around the eyes to prevent crow's feet, i.e. fine lines around the eyes. See column 5, lines 35-39. The composition softens the keratinous layer. See column 1, lines 7-20.

Jokura is considered to anticipate the instant invention since Jokura's cosmetic composition requires a salt of a dicarboxylic acid, i.e. it is a critical component of the composition, and that the dicarboxylic acid species and the salt species disclosed are sufficiently limited in that one immediately envisage the instant malonic acid salt.

With regard to the recitation of "wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test", it is the examiner's position that Jokura's composition will inherently have a Flexibility value of greater than 1 and the rationale is as follows: Firstly, the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Secondly, the prior art teaches the same malonic acid salt and in the same weight percent. Therefore, since the prior art's composition and the instant composition, which recites open-claim language, are identical, it is the examiner's

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position that they will exhibit the same property, i.e. the instant flexibility value. It should be noted that once an examiner has presented evidence or reasoning tending to show inherency, the burden shifts to the applicant to show it is not inherent. See MPEP 2112.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract. The composition is used for treating dry skin in the winter and applicable to the skin around the eyes to prevent crow's feet, i.e. fine lines around the eyes. See column 5, lines 35-39. The composition softens the keratinous layer. See column 1, lines 7-20.

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Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid . The dicarboxylic acid salt (C) include alkali metal (for example, sodium, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; **alkanolamine** (for example, triethanolamine) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. Note that the term amine encompasses Jokura's alkanolamines, arginine, lysine, and ammonium. These dicarboxylic acid salt may be added in the form of a salt at the step of the preparation of the skin cosmetic of the present invention. Alternatively, an acid may be added followed by the addition of an alkali (sodium hydroxide, etc.) to thereby form the aimed salt via *neutralization* in the system. To achieve a sufficient moisturizing effect while avoiding excessive irritation, it is preferable that the content of components (B) and (C), in the skin cosmetic of the present invention falls within a range of from 0.01 to 20% by weight, still preferably from 0.05 to 15% by weight and still preferably 0.01 to 10% by weight. To achieve a sufficient moisturizing effect while avoiding irritation due to the acid, it is preferable that the molar ratio of the components (B) to (C) falls within a range of from 1/9 to 9/1, still preferably from 2/8 to 8/2. See column 3, lines 30-60. Furthermore, Jokura teaches regulating the pH value of the skin cosmetic, which contains the components (B) and (C), to pH 3 to 10, still preferably to pH 3 to 9, to avoid the irritation observed at a pH value less than 3 or exceeding 10. See column 3, lines 60-65. The examples utilize a pH of 4.1. When oily substances are used as the carrier, the content of the oily substance in is a range from 0.01 to 50% by weight. See column 4, lines 14-16. When water, ethanol and/or water-soluble polyhydric alcohols are employed as the carrier, the content is preferably from 0.01 to 95% by weight. See column 4, lines 30-35.

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Jokura et al do not specify the acid to salt molar ratio of component (C).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Jokura et al and manipulate the acid to salt ratio of component (C). One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent) adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Jokura teaches the importance of avoiding skin irritation due to the acid; thus the pH must be above 3 and below 10 (see column 3, lines 30-65). Therefore, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render a pH that does not irritant the skin wherein using equimolar amounts of the salt and acid (full neutralization) would contribute to the overall increase of the pH of the composition whereas partial neutralization of the acid would contribute to the overall decrease of the pH of the composition since the compound is in a slightly acidic form. Additionally, it should be noted that generally differences in concentrations, such as the instantly claimed molar ratio of acid to salt, do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to the recitation of “wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test”, the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Further, Table VIII of the instant specification discloses ammonium malonate exhibits a value of

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1.36. Thus, it is the examiner's position that Jokura's composition would implicitly have a Flexibility value of greater than 1 if a malonic acid salt is utilized in Jokura's composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9 of copending Application No. 10/347982.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Instant application '731 independent claim 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1:1000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 5 is directed to

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amine salts including mono-hydroxy substituted amine salts (dimethylethanolamine).

Independent claim 6 is directed to a method controlling the signs of aging by using a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test.

Co-pending application '982 independent claims 1 and 6 are directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a mono-hydroxy substituted amine salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claims 2 and 7 are specifically directed to a dimethylaminoethanol. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 5 is directed to a pH of 4-7. Independent claim 9 is directed to a method of controlling the signs of aging by using a cosmetic composition comprising: ((i) from about 0.0001 to about 30% by weight of a mono-hydroxy substituted amine salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier.

The difference between the instantly claimed composition and '982 is copending application's specifically recites "mono-hydroxy substituted amine salt" and the instant independent claim is directed to the broad scope of a "malonic acid salt". Therefore, the instant claims encompass the subject matter of '982. Moreover, the instant claim dependent 5 specifically recites dimethylethanolamine in a Markush group, which is a mono-hydroxy substituted amine salt. With regard to the functional limitation of '731 "flexible value of greater

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than 1 in the porcine skin test”, the examiner points out that ‘731 specification page 5 discloses that the malonate salts themselves provide this limitation; thus since both applications have the same components in the same concentration, both will have the same property. Therefore, the instant application encompasses the subject matter of the copending application ‘982 and is rejected under obviousness double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/374300.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Instant application ‘731 independent claim 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1:1000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, and ammonium (amine). Dependent claim 5 is directed to specific organic amine salts. Independent claim 6 is directed to a method controlling the signs of aging by using a cosmetic composition

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comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test.

Copending application '300 independent claim 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of salt which is an amine neutralized malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier, wherein the composition has a pH ranging from about 1.8-6.5. Dependent claim 2 is specifically directed to ammonia as the amine. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 5 is directed to a pH of 3-5.5. Independent claim 6 is directed to a method of controlling the signs of aging by using a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of salt which is an amine neutralized malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier, wherein the composition has a pH ranging from about 1.8-6.5.

The difference between the instant composition and '300 is that copending application claims a specific salt, i.e. amine, of malonic acid and a specific pH range. However, the instant application claims encompass the subject matter of '300 since the instant application is directed to the genus, i.e. a salt of malonic acid. Moreover, the instant dependent claims 4 and 5 recite an amine salt in a Markush group, i.e. ammonium in instant claim 4 and organic amines in instant claim 5. With regard to the functional limitation of '731 "flexible value of greater than 1 in the porcine skin test", the examiner points out that '731 discloses that the malonate salts themselves

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provide this limitation; thus since both applications have the same components in the same concentration, both will have the same property. Thus, the instant application encompasses the subject matter of copending application '300 and thus is rejected under obviousness double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 7 of copending Application No. 10/601819 in view of Clark (Dermatology Times, February 2002, pg. 78).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Instant application '731 independent claim 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1:1000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, and ammonium (amine). Dependent claim 5 is directed to specific organic amine salts. Independent claim 6 is directed to a method controlling the signs of aging by using a cosmetic composition

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comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test.

Co-pending application '819 independent claims 1 is directed to a cosmetic composition comprising: (i) a first amine present as a neutralized counterion salt of a C2-C4c carboxylic acid other than an alpha- or beta-hydroxycarboxylic acid; (ii) a second amine different from the first amine and having a molecular weight no lower than about 100; (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to malonic acid. Dependent claim 7 is specifically directed to dimethylaminoethanol as the first amine (the amine salt of the carboxylic acid).

The instant application does not claim a secondary amine.

Clark of Dermatology Times teaches the use of dimethylaminoethanol for treating wrinkles. See page 78.

The difference between the instant application and '819 is firstly '819 claims an additional component, i.e. a secondary amine. However, the instant claim language is open-ended and can include additional components such as the secondary amine of copending application. One would have been motivated to add an additional amine to the cosmetic composition of the instant application, if one wanted to render a cosmetic composition to treat wrinkles wherein the use of a secondary amine would yield an additive effect in treating wrinkles, as taught by Clark.

Further, '819 independent claim is directed to a C2-C40 acid amine salt which is generic for the carboxylic acid. However, dependent claim 2 of '819 is directed to malonic acid

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specifically. Additionally, '819 independent claim is specifically directed to an amine salt of acid. However, instant claim 4 and 5 also claim amine salts. With regard to the functional limitation of '731 "flexible value of greater than 1 in the porcine skin test", the examiner points out that '731 discloses that the malonate salts themselves provide this limitation; thus since both applications have the same components in the same concentration, both will have the same property.

Thus, since instant application and copending application '819 are both directed to overlapping subject matter wherein both claim a cosmetic composition comprising the critical components (i) 0.0001-30 % amine salt of malonic acid and (ii) 1-99.9% of a carrier; they are said to be obvious modifications of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/601856 in view of JP 61215318 (entire document).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

Instant application '731 independent claim 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a

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fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1:1000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, and ammonium (amine). Dependent claim 5 is directed to specific organic amine salts. Independent claim 6 is directed to a method controlling the signs of aging by using a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test.

Copending application '856 is directed to a cosmetic composition comprising: from about 0.0001 to about 30% by weight of a salt of malonic acid; (ii) from about 0.05 to about 40% by weight of an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1:1000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 5 is directed to amine salts.

Instant application does not specifically claim a sunscreen with a UV range of 280-400nm.

JP '318 teaches a skin composition for lowering skin's UV-absorptivity. The composition contains (i) an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; (ii) a organic sunscreen

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Parsol 1789 (4,4-t-butyl-methoxydibenzoylmethane with a UV radiation of 280-400nm), and (iii) an emulsion base (carrier).

The difference between the instant application and '856 is that '856 independent claim is recites a sunscreen. However, the instant claim language is open for additional components such as '856 's organic sunscreen. Therefore, the inclusion of a sunscreen is an obvious modification if one desired to formulation a cosmetic sunscreen as taught by JP '318. With regard to the functional limitation of '731 "flexible value of greater than 1 in the porcine skin test", the examiner points out that '731 discloses that the malonate salts themselves provide this limitation; thus since both applications have the same components in the same concentration, both will have the same property.

Thus, since instant application and copending application '856 are both directed to overlapping subject matter wherein both claim a cosmetic composition comprising the critical components (i) 0.0001-30 % amine salt of malonic acid and (ii) 1-99.9% of a carrier; they are considered be obvious modifications of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/767679 in view of Nakatsu et al (5,965,518).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to similar subject matter.

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Instant application '731 independent claim 1 is directed to a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test. Dependent claim 3 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1:1000. Dependent claim 4 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, and ammonium (amine). Dependent claim 5 is directed to specific organic amine salts. Independent claim 6 is directed to a method controlling the signs of aging by using a cosmetic composition comprising: (i) from about 0.0001 to about 30% by weight of a salt of malonic acid; and (ii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier; wherein the composition exhibits a flexible value of greater than 1 in the porcine skin test.

Co-pending application '679 independent claim 1 is directed to a cosmetic composition comprising: (i) 0.001-10% of a fragrance comprising a terpenoid, (ii) from about 0.0001 to about 30% by weight of salt which is an amine neutralized malonic acid; and (iii) from about 1 to about 99.9% by weight of a cosmetically acceptable carrier. Dependent claim 2 is directed to the molar ratio of acid: salt wherein the malonic acid is present as a half neutralized and a fully neutralized acid in a molar ratio ranging from about 1000:1 to about 1 :1 000. Dependent claim 3 is directed to a molar ratio is about 2:1 to about 1:200. Dependent claim 4 is directed to a cationic counterion selected from lithium, sodium, potassium, magnesium, calcium, ammonium and combinations. Dependent claim 5 is directed to same amine salts.

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Instant application does not claim a terpene fragrance.

Nakatsu teaches the use of a terpenoid not only produces a fragrance but also a antimicrobial effect. See column 2, lines 55-60.

The difference between the instant application and '679 is that '679 independent claim recites a terpenoid fragrance. However, the instant claim language is open for additional components such as '679 's fragrance. Therefore, the inclusion of a fragrance is an obvious modification if one desired to formulation to impart a fragrance to a cosmetic composition. Moreover, a skilled artisan would have been motivated to use a terpenoid fragrance in particular since a terpenoid not only imparts a pleasant odor but it has antimicrobial activity. With regard to the functional limitation of '731 "flexible value of greater than 1 in the porcine skin test", the examiner points out that '731 discloses that the malonate salts themselves provide this limitation; thus since both applications have the same components in the same concentration, both will have the same property.

Thus, since instant application and copending application '679 are both directed to overlapping subject matter wherein both claim a cosmetic composition comprising the critical components (i) 0.0001-30 % amine salt of malonic acid and (ii) 1-99.9% of a carrier; they are considered obvious modifications of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

All the claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616



SSG